

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9075

Bartle, J.

May 29, 2013

Gahla R. Towery ("Ms. Towery" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Dominic M. Pedulla, M.D., F.A.C.C. Dr. Pedulla is no stranger to this litigation. According to the Trust, he has signed at least 128 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated January 3, 2003, Dr. Pedulla attested in Part II of Ms. Towery's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

dimension.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$486,424.⁴

In the report of claimant's echocardiogram, Dr. Pedulla stated that claimant had "[m]oderate mitral regurgitation." Dr. Pedulla, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In March, 2006, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists. In audit, Dr. Mikati concluded that there was no reasonable medical basis for Dr. Pedulla's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mikati stated, "Black pixels were included to

3. Dr. Pedulla also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

inflate [mitral regurgitation] jet to reach [the] moderate cutoff."

Based on Dr. Mikati's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Towery's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant submitted a letter from Dr. Pedulla wherein he confirmed his finding of moderate mitral regurgitation. In support of his finding, Dr. Pedulla explained that "[t]he inclusion of small areas of black pixels was inadequate to amount to an overestimate" and that the "left atrium area was overestimated leading to a clear-cut 'moderate' quantitation." Claimant also argued that the auditing cardiologist substituted his opinion for that of the attesting physician.

The Trust then issued a final post-audit determination, again denying Ms. Towery's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Towery's claim.

show cause why Ms. Towery's claim should be paid. On October 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6619 (Oct. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 28, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Towery merely refers the court to the arguments she made in contest. In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim because neither claimant nor Dr. Pedulla rebuts the specific finding of the auditing cardiologist that black pixels were included to inflate the appearance of mitral regurgitation. According to the Trust, the inclusion of non-regurgitant, low-velocity black pixels and overtracing the amount of regurgitation are indicia of an opinion beyond the bounds of medical reason.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Towery had moderate mitral regurgitation. Specifically, Dr. Abramson observed:

Based on my review of the Special Master Record, including the reports of the Attesting Physician, the Auditing

Cardiologist, and the transthoracic echocardiogram dated 1/03/03, the above-named diet-drug recipient does not have moderate [mitral regurgitation]. There is no reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Gahla R. Towery has moderate [mitral regurgitation]. She has mild regurgitation.

....

In reviewing the transthoracic echocardiogram from 1/03/03, my visual estimate is that there is only mild mitral regurgitation. The mitral regurgitant jets are all brief, early systolic jets occupying less than one-third of systole, which is typical of mild regurgitation. Significant mitral regurgitant jets are holystolic. Several cardiac cycles in each view have no mitral regurgitation. I measured the mitral regurgitant jet and the left atria area (in the same frame) in three cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $3.6 \text{ cm}^2/24.8\text{cm}^2$, $4.2\text{cm}^2/25.9\text{cm}^2$ and $3.1\text{cm}^2/23.8\text{cm}^2$. These ratios are 15%, 16%, and 13%, all of which are less than 20%, and are consistent with mild mitral regurgitation.

The measurement on the tape performed by the technologist, included non-regurgitant areas within the mitral regurgitant jet, and an undertraced left atrial area, accounting for the RJA/LAA of 26%.

In response to the Technical Advisor Report, claimant argues that Dr. Abramson should not have concluded that her review was not performed in accordance with the standards set forth in the Settlement Agreement. Ms. Towery also states that she stands by Dr. Pedulla's explanation. Claimant further argues that Dr. Abramson did not explain why two of her RJA/LAA calculations did not use an abnormal left atrial dimension, did

not state how that would affect her calculations, and did not identify the frames she measured or whether they were used by the attesting physician. Finally, claimant argues that Dr. Abramson went beyond the question she was asked when she stated that "it would be impossible for a reasonable echocardiographer to interpret the severity of this mitral regurgitation as moderate."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's contention, the letter from Dr. Pedulla does not establish a reasonable medical basis for his Green Form representation that claimant had moderate mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Pedulla conceded that black pixels were included but argued there was an inadequate amount to result in an overestimate. Dr. Mikati, however, concluded that "[b] lack pixels were included to inflate [mitral regurgitation] jet to reach moderate cutoff."⁷ In addition, Dr. Abramson determined that the "measurement on the tape performed by the technologist, included non-regurgitant areas within the mitral regurgitant jet, and an undertraced left atrial area." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation. To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Towery's claim for Matrix Benefits.

7. Thus, we reject claimant's argument that Dr. Mikati simply substituted his opinion for that of Dr. Pedulla.